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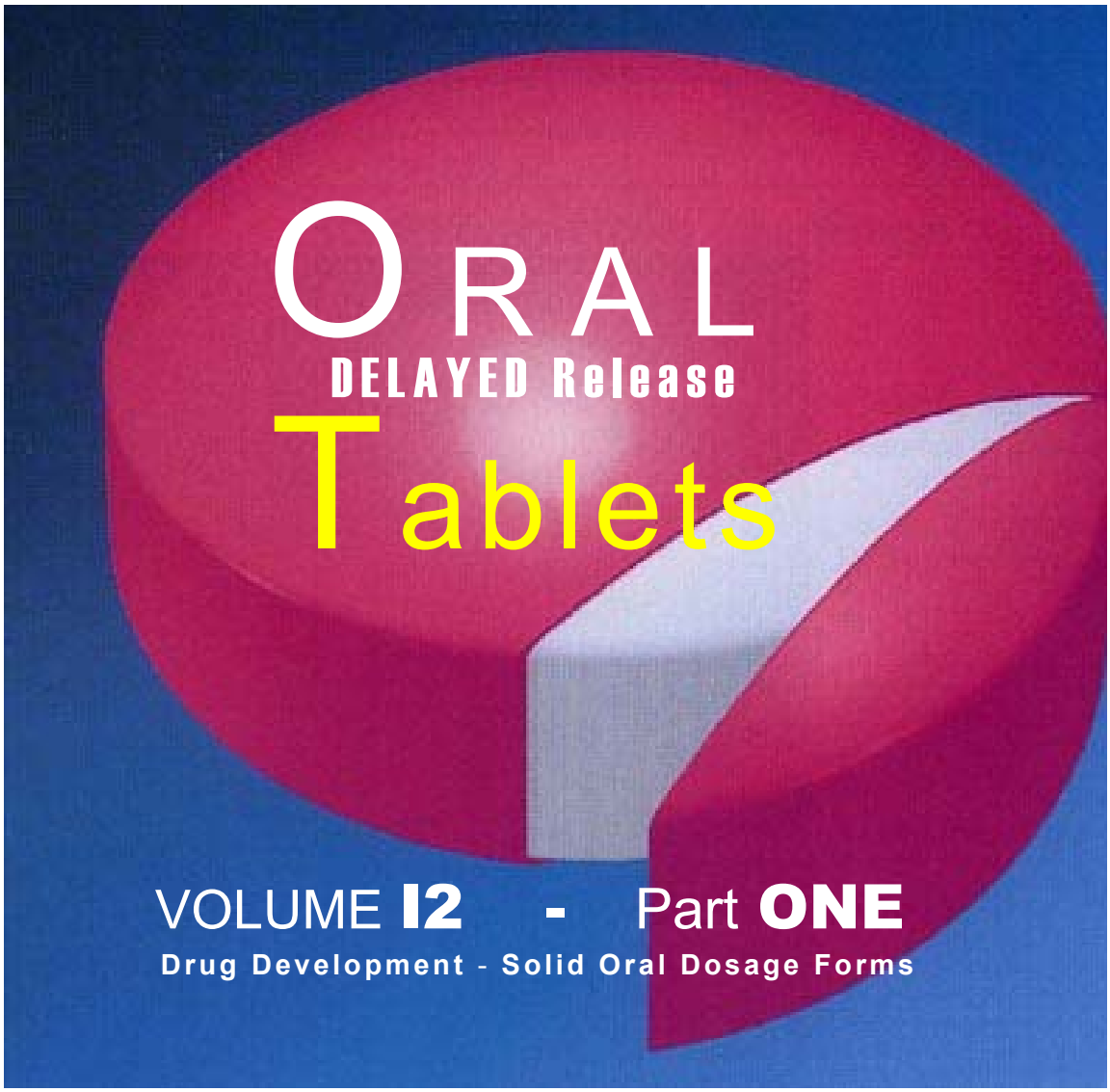

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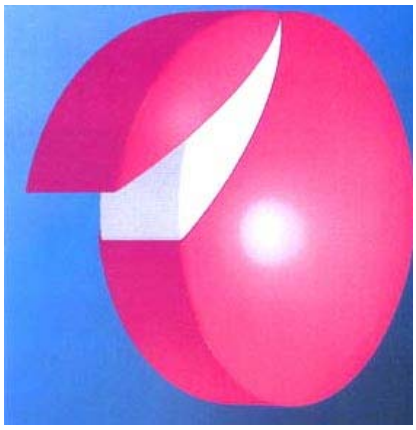

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Part ONE

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ORAL

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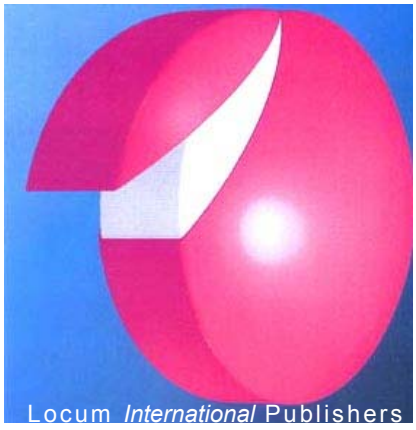

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INTRODUCTION

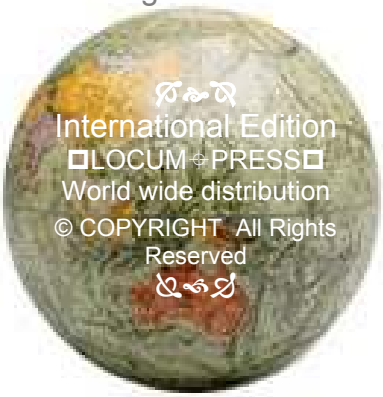
Handbook of Generic Development - Oral DR Tablet

This handbook is the **new expanded** international edition of the ongoing **24** Volume *Series* under the cumulative title of Handbook of Generic Drug Development. It is a hands-on, technical presentation that portrays the current drug requirement steps necessary at the time of going to print, of the Abbreviated New Drug Application for oral DR tablet dosage forms. It is written in two parts from pre-formulation drug development to a representative ANDA covering all the aspects of the drug development process required for solid oral DR dosage forms. The Handbook is available in electronic format (CD ROM) and **e-**format (PDF online). The Handbook is up-dated to current regulatory requirements once or occasionally under exceptional circumstances, when new important FDA guidelines appear, twice annually. Complete updates are available without charge to Association Members of the Drug Development Association - IAGIM.

This handbook provides a proven pathway to solid oral DR dosage form development. Modern commercial formulations highlight the common tablet/caplet development routes namely the classical wet granulation, spray granulation, dry granulation and finally slugging with direct compression. Low active dosage (<10mg) and high potency (>50%) examples are specially chosen to demonstrate the formulation steps and process stages as a prerequisite to developing stable, elegant and rugged enteric coat for tablet formulations.

This Handbook edition includes additional data on analytical method and FP process validation has been redesigned to meet the Guidance for Industry - Organization of an Abbreviated New Drug Application as well as all key draft and final FDA guidelines and requirements of the Center of Drug Evaluation and Research (CDER) to date of publishing.

Editor-in-Chief.



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